



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/635,679 | 08/10/2000 | Joel F. Habener | 0609.1090009/MAC | 6862 |

26111 7590 08/28/2002

STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W., SUITE 600
WASHINGTON, DC 20005-3934

EXAMINER

MINNIFIELD, NITA M

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 08/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/635,679

Applicant(s)

HABENER, JOEL F.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-28 is/are pending in the application.
- 4a) Of the above claim(s) 20-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 45 sheets
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 15, 35 sheets
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of species B, claim 19, and SEQ ID NO: 3, in Paper No. 13 (filed May 28, 2002) is acknowledged. The traversal is on the ground(s) that each species is related to the same starting amino acid sequence and thus search of all the claims would not be undue. This is not found persuasive because the search for each specific amino acid sequence is different. The different substitutions (i.e. any amino acid substituted, any hydrophobic amino acid substituted, any basic amino acid substituted, or any aromatic amino acid substituted) require separate searches and separate enablement considerations. The search for each of the above species is not co-extensive particularly with regard to the literature search. A reference, which would anticipate one species, would not necessarily anticipate or make obvious any of the other species. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 20-28 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

3. Claims 15-19 are being examined in the pending application.
4. Claims 15-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to derivatives of GLP-1 (7-37), wherein the amino acid sequence of said derivative has the same number of amino acids as said GLP-1 (7-37) and at least 80% amino acid identity to said GLP-1 (7-37) and wherein said derivative has an insulintrophic activity that exceeds the insulintrophic activity of GLP-1 (1-37) and GLP-1 (7-37).¹⁻³⁶ The specification teaches one of skill in the art how to make the claimed derivative; however not the characteristics (said derivative has an insulintrophic activity that exceeds the insulintrophic activity of GLP-1 (1-37) and GLP-1 (7-37)).¹⁻³⁶ and how to use the claimed derivative. The specification has not shown that the claimed analog or derivative (SEQ ID NO: 3), a derivative that has a hydrophobic amino acid being substituted with a different hydrophobic amino acid residue (i.e. leucine for isoleucine). The art teaches that synthetic peptide analog GLP-1 (1-36)-NH₂ stimulates adenylate cyclase activity in brain and pituitary membranes and weakly stimulates insulin release from isolated rat pancreatic islets in the presence of glucose (Drucker et al 1987; p. 3434; p. 3436). The specification is not enabled for the claimed invention.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(f) he did not himself invent the subject matter sought to be patented.

6. Claims 15-19 are rejected under 35 U.S.C. 102(a) as being anticipated by Komatsu et al 1988 or Mojsov NIH Grant Application, 1987.

Komatsu et al disclose a derivative of GLP-1 (7-37), the GLP-1 (7-36) that is a truncated form of GLP-1 (abstract). Komatsu et al disclose that insulin release was significantly stimulated by this peptide derivative (abstract; p. 203, col. 1; p. 205, col. 2). The increase in insulinotrophic activity was greater than the insulinotrophic activity of GLP-1 (1-37).

Mojsov NIH Grant Application 1987 discloses derivatives of GLP-1 (7-37) (p. 13; p. 16). Mojsov discloses the synthesis of analogs of GLP-1 (7-37) (p. 24-27) and assaying these analogs for insulinotrophic activity (p. 27-28).

The derivatives appear to be the same. Since the Patent Office does not have the facilities for examining and comparing applicants' derivative with the derivative of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed derivative and the derivative of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

7. Claims 15-19 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The prior art of Mojsov NIH Grant Application provided by Applicant indicates that Applicant is not the sole inventor of the claimed invention. Mojsov is listed as the principal investigator on the NIH Grant Proposal, but Mojsov is not listed as an inventor in the pending patent application.

8. No claims are allowed.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

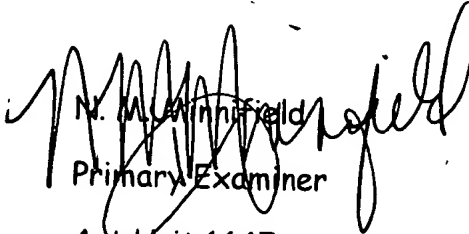
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Application/Control Number: 09/635,679
Art Unit: 1645

Page 6

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


N. M. Winnifield
Primary Examiner
Art Unit 1645

Nmm

August 19, 2002